Complete Summary

GUIDELINE TITLE

Emergency contraception.

BIBLIOGRAPHIC SOURCE(S)

Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. FFPRHC Guidance (April 2006). Emergency contraception. J Fam Plann Reprod Health Care 2006 Apr;32(2):121-8; quiz 128. [65 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. Emergency contraception. Aberdeen (Scotland): Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit; 2003 Jun. 7 p. [53 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Unprotected sexual intercourse
- Sexual intercourse with potential contraceptive failure
- Unintended pregnancy
- Sexually transmitted infection (STI)

GUIDELINE CATEGORY

Counseling
Evaluation
Management
Prevention
Risk Assessment
Treatment

CLINICAL SPECIALTY

Emergency Medicine
Family Practice
Internal Medicine
Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Patients
Pharmacists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To provide clinicians information on the safe and effective use of emergency contraception
- To update and replace the previous Faculty recommendations on emergency contraception

TARGET POPULATION

Women seeking emergency contraception

INTERVENTIONS AND PRACTICES CONSIDERED

Medical History (Including Sexual History) and Clinical Examination; Testing for *Chlamydia trachomatis*; Prophylactic Antibiotics

1. Counseling patients regarding emergency contraception to help them make informed choices
2. Emergency contraception including:
    - Oral progestogen-only emergency contraception (POEC) (levonorgestrel [Levonelle-2®, Levonelle-1500®])
    - Copper intrauterine contraceptive devices (IUDs)

Note: Mifepristone has been shown to be an effective emergency contraception when taken as a single dose up to 120 hours after unprotected sexual intercourse. However, it is not licensed nor readily available for this indication in the UK.

3. Follow-up including pregnancy test if needed and information and counseling on use of contraceptive methods

MAJOR OUTCOMES CONSIDERED

Safety, Efficacy, and Cost-effectiveness of Emergency Contraception

- Failure rates of emergency contraception (EC) methods, unintended pregnancy rate
- Drug interactions and side effects associated with oral hormonal EC
- Pelvic infection rate after intrauterine device insertion

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Electronic searches were performed for: MEDLINE (CD Ovid version) (1996–2006); EMBASE (1996–2006); PubMed (1996–2006); The Cochrane Library (to December 2005) and the US National Guideline Clearing House. The searches were performed using relevant medical and subject headings (MeSH), term and text words. The Cochrane Library was searched for systematic reviews, meta-analyses and controlled trials relevant to emergency contraception. Previously existing guidelines from the Faculty of Family Planning and Reproductive Health Care, the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization, and reference lists of identified publications were also searched. Similar search strategies have been used in the development of other national guidelines.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Selected key publications were appraised according to standard methodological checklists before conclusions were considered as evidence. Evidence was graded using a scheme similar to that adopted by the Royal College of Obstetricians and Gynaecologists (RCOG) and other guideline development organizations.

Evidence tables (available on the Faculty Web site [www.ffprhc.org.uk]) summarise relevant published evidence on emergency contraception (EC), which was identified and appraised in the development of this Guidance.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Draft One Guidance document is written, providing recommendations and good practice points based on the literature review. The Clinical Effectiveness Unit must take overall responsibility for writing the Guidance document. The Multidisciplinary Group and other peer reviewers should highlight inconsistencies and errors or where the text is incomprehensible.

A Multidisciplinary Group Meeting is held, comprising stakeholders and including service user representation, representation from the Faculty of Family Planning and Reproductive Health Care (FFPRHC) Education Committee and, where possible, representation from the FFPRHC Clinical Effectiveness Committee (CEC) and FFPRHC Council. A one-day meeting is held in Aberdeen with the Multidisciplinary Group to discuss the Draft One Guidance document.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendations

A: Evidence based on randomised controlled trials (RCTs)

B: Evidence based on other robust experimental or observational studies

C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point: Where no evidence exists but where best practice is based on the clinical experience of the expert group

COST ANALYSIS

Emergency contraception (EC) appears to be cost-effective, whether it is provided on request or as an advance supply to be used when needed. A greater use of EC could reduce the medical and social costs of unintended pregnancy.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The Draft Two Guidance document is peer reviewed by the Multidisciplinary Group and the Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Committee (FFPRHC CEC). All written feedback on the Draft Two Guidance document is tabulated and the Clinical Effectiveness Unit (CEU) response to these comments is outlined. The Draft Three Guidance document is prepared on written feedback and is sent to the Multidisciplinary Group and the FFPRHC CEC. Only minor comments can be accepted at this stage. The Final Guidance document is published by the FFPRHC. Proof reading of the Guidance is then performed by three members of the CEU team independently and comments collated and sent back by the Unit Director. A PDF version of the Guidance is made available on the FFPRHC website.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the grades of recommendation, based on levels of evidence (A-C, Good Practice Point), are provided at the end of the "Major Recommendations" field.

When Is Emergency Contraception Indicated?

1. The clinician should summarise evidence of effectiveness and the need for emergency contraception (EC) in each woman's individual circumstance to allow her to make an informed choice regarding its use (**Good Practice Point**).

Table. Recommendations for Emergency Contraception Use in Commonly Occurring Situations

Situation	Indications for Emergency Contraception
Potential Failures of Various Contraceptive Methods	
Combined pills (21 active tablets)	If *three or more* 30 to 35 microgram EE or *two or more* 20 microgram EE pills have been missed in the first week of pill taking (i.e., Days 1 to 7) and UPSI occurred in Week 1 or the pill-free week

Situation	Indications for Emergency Contraception
Progestogen-only pill (POP)	If *one or more* POPs have been missed or taken >3 hours late (>12 hours late for Cerazette®) *and* UPSI has occurred in the 2 days following this
Intrauterine contraception	If complete or partial expulsion is identified or mid-cycle removal of an IUD/IUS is deemed necessary *and* UPSI has occurred in the last 7 days
Progestogen-only injectables	If the contraceptive injection is late (>14 weeks from the previous injection for medroxyprogesterone acetate or >10 weeks for norethisterone enantate) *and* UPSI has occurred
Barrier methods	If there has been failure of a barrier method
Use of Liver Enzyme Inducers	
Liver enzyme inducing drugs (including St. John's Wort)	An additional barrier method is recommended if oral contraceptives, progestogen implants or contraceptive patch and liver enzyme-inducers are taken concurrently. EC is indicated if there is UPSI or barrier method failure during, or in the 28 days following, use of liver enzyme-inducers

EC, emergency contraception; EE, ethinylestradiol; IUD, intrauterine device; IUS, intrauterine system; POP, progestogen-only pill; UPSI, unprotected sexual intercourse.

What Regimens of Oral Hormonal Emergency Contraception Are Available?

2. Levonorgestrel (LNG) should be given as a single 1.5 mg dose as soon as possible after unprotected sexual intercourse (UPSI), and within 72 hours (**Grade A**).

How Effective Is Emergency Contraception and How Can Efficacy Be Optimised?

3. Women should be given written and verbal information regarding the failure rates of oral and intrauterine EC to allow them to make informed choices and to increase compliance and efficacy (**Grade A**).
4. LNG EC may be considered between 73 and 120 hours after UPSI, but women should be informed of the limited evidence of efficacy, that such use is outside product licence, and the alternative of an IUD (**Good Practice Point**).
5. Women can be advised that LNG EC can be used more than once in a cycle if clinically indicated (**Good Practice Point**).
6. An intrauterine device (IUD) (or advice on how to obtain one) should be offered to all women attending for EC even if presenting within 72 hours of UPSI (**Good Practice Point**).
7. IUDs with banded copper on the arms and containing at least 380 mm^2 of copper have the lowest failure rates and should be the first-line choice, particularly if the woman intends to continue the IUD as long-term contraception (**Grade A**).
8. Ideally, an emergency IUD should be fitted at first presentation, but insertion can be offered later, at the woman's convenience. In this case, LNG EC should be given in the interim (**Good Practice Point**).
9. If facilities are unavailable for emergency IUD insertion, local referral mechanisms should facilitate timely access to a specialist who can provide this service (**Good Practice Point**).
10. A copper IUD can be inserted up to 5 days after the first episode of UPSI. If the timing of ovulation can be estimated, insertion can be beyond 5 days of UPSI, as long as it does not occur beyond 5 days after ovulation (**Grade C**).

Are There Any Contraindications to Emergency Contraception?

11. The World Health Organization *Medical Eligibility Criteria for Contraceptive Use* advises that there are no medical contraindications to the use of hormonal EC (**Grade C**).

What Drug Interactions Are Relevant to Emergency Contraceptive Use?

12. Women using liver enzyme-inducing drugs should be advised that an IUD is the preferred option for EC (**Grade A**).
13. Women who are using liver enzyme-inducing drugs who are given 0.75 mg tablets of LNG (Levonelle-2) should be advised to take a total of 2.25 mg (three tablets) as a single dose, as soon as possible and within 72 hours of UPSI. This use is outside the product licence (**Grade C**).
14. Women who are using liver enzyme-inducing drugs who are given 1.5 mg tablets of LNG (Levonelle One Step or Levonelle 1500) should be advised to take a total of 3 mg (two tablets) as a single dose, as soon as possible and within the 72 hours of UPSI. This use is outside the product licence (**Good Practice Point**).
15. Women using non-liver enzyme-inducing antibiotics (short- or long-term) should follow the normal LNG regimen (1.5 mg within 72 hours of UPSI) (**Grade C**).
16. There are no drugs that are known to affect emergency IUD use (**Grade C**).

What Clinical Examinations and Investigations Are Required Before Providing Emergency Contraception?

17. A sexual history should be taken from all women attending for EC to assess risk of sexually-transmitted infections (STIs) (**Grade C**).
18. Prior to emergency IUD insertion, women at higher risk of STIs (age <25 years, change in sexual partner, or more than one partner in the last year) should be offered testing for *Chlamydia trachomatis* (as a minimum) (**Grade C**).
19. For women assessed as being at higher risk of STIs, if results of testing are not available at the time of emergency IUD insertion, the use of prophylactic antibiotics may be considered (**Good Practice Point**).

What Are the Side Effects of Emergency Contraception?

20. Women who experience vomiting within 2 hours of administration of LNG EC should be advised to return as soon as possible for a repeat dose (**Good Practice Point**).
21. Women should be advised that a small increase in pelvic infection occurs in the 20 days following IUD insertion, but the risk is the same as for the non-IUD-using population thereafter (**Grade A**).

What Aftercare and Follow-Up Is Required?

22. Women should be given information and counselling on use of their future contraceptive method of choice (**Good Practice Point**).
23. LNG EC does not provide contraceptive cover for the remainder of the cycle and effective contraception or abstinence must be advised (**Grade B**).
24. Women should be advised to have a pregnancy test if their expected menstruation is more than 7 days late, or lighter than usual (**Grade B**).
25. An emergency IUD can be removed at any time after the next menstruation if no UPSI has occurred since menses or if hormonal contraception was started within the first 5 days of that cycle (**Grade C**).

Who Can Supply Emergency Contraception?

26. Patient group directions (PGDs) can be developed to allow nurses and other health care professionals to supply and administer contraceptives. PGDs may include use outside the terms of the product licence provided such use is justified by current best practice; the PGD clearly describes the status of use outside the licence; and the documentation includes the reason why such use is necessary (**Grade C**).

Emergency Contraception and Young People

27. If a young person is assessed for competency, this should be documented in case notes as being 'Fraser ruling competent' (advice understood, will have or continue to have sex, advised to inform parents, in best interest) (**Grade C**).

Should Emergency Contraception Be Supplied in Advance of Need?

28. Advance provision of LNG can be offered to women to increase early use when required (**Grade A**).

Definitions:

Grades of Recommendation based on levels of evidence as follows:

A: Evidence based on randomised controlled trials (RCTs)

B: Evidence based on other robust experimental or observational studies

C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point: Where no evidence exists but where best practice is based on the clinical experience of the Expert Group

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified for each recommendation (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate use of emergency contraception
- Prevention of unintended pregnancy

POTENTIAL HARMS

- Oral and intrauterine emergency contraception (EC) methods can fail and result in unintended pregnancy.
- Women may experience nausea and vomiting after administration of levonorgestrel (LNG) EC.
- Disturbances in the menstrual cycle are common after LNG EC. It may be difficult to differentiate between non-menstrual bleeding in the early days after EC and actual menstruation. Clinicians and women should always err on the side of caution, and undertake pregnancy testing if there is any doubt that menstruation has followed EC use.
- The Summary of Product Characteristics advises caution in use of LNG in women with hepatic dysfunction, hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption. Women with severe malabsorption syndromes (such as Crohn's disease) may

experience a reduction in efficacy of oral EC. Additionally, any women known to have hypersensitivity to LNG or any of the other components of the tablet should use oral EC with caution.
- Liver-enzyme inducing drugs (including the herbal remedy, St John's Wort) may reduce the efficacy of hormonal contraceptives by increasing the metabolism of ethinylestradiol and progestogens.
- A small increase in pelvic infection occurs in the 20 days following intrauterine device (IUD) insertion, but the risk is the same as for the non-IUD-using population thereafter.
- Caution is advised when prescribing oral EC for women using the anticoagulant drugs, phenindione and warfarin. It has been observed that anticoagulant effects may be altered following LNG use. Women should be advised about potential drug interactions and attention should be paid to their anticoagulation monitoring.

CONTRAINDICATIONS

CONTRAINDICATIONS

Use of an intrauterine device for emergency contraception (EC) carries the same contraindications as does routine intrauterine device (IUD) insertion (refer to the National Guideline Clearinghouse [NGC] summary of the Faculty of Sexual and Reproductive Healthcare [FFPRHC] guideline The Copper Intrauterine Device as Long-Term Contraception).

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Staff Training/Competency Material

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. FFPRHC Guidance (April 2006). Emergency contraception. J Fam Plann Reprod Health Care 2006 Apr;32(2):121-8; quiz 128. [65 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Jun (revised 2006 Apr)

GUIDELINE DEVELOPER(S)

Faculty of Sexual and Reproductive Healthcare - Professional Association

SOURCE(S) OF FUNDING

Faculty of Sexual and Reproductive Healthcare

GUIDELINE COMMITTEE

Clinical Effectiveness Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Clinical Effectiveness Unit (CEU): Ms Lisa Allerton (Research Assistant), Dr Gillian Penney (Director), Dr Susan Brechin (Co-ordinator) and Ms Gillian Stephen (Research Assistant) Ms Lisa Allerton (Research Assistant), Dr Gillian Penney (Director), Dr Susan Brechin (Co-ordinator) and Ms Gillian Stephen (Research Assistant)

Clinical Effectiveness Committee: Dr Kirsten Black (Associate Specialist, Lambeth Primary Care Trust), Dr Karen Fairhurst (Senior Lecturer, Divison of Community Health Science – GP section, University of Edinburgh), Dr Gillian Flett (Consultant in Sexual and Reproductive Health, Square 13, Centre for Sexual and Reproductive Health, NHS Grampian, Aberdeen), Ms Lorraine Forster (Clinical Governance Coordinator, Sandyford Initiative, Glasgow), Dr Noreen Khan (Consultant in Community Gynaecology and Sexual Health, Charlestown Sexual Health Clinics, North Manchester PCT) and Dr Anne Webb (Consultant in Family Planning and Reproductive Health Care, Abacus Clinics for Contraception and Sexual Health, Liverpool)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. Emergency contraception. Aberdeen (Scotland): Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit; 2003 Jun. 7 p. [53 references]

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Faculty of Sexual and Reproductive Healthcare Web site.

Print copies: Available from the Faculty of Sexual and Reproductive Healthcare, 27 Sussex Place, Regent's Park, London NW1 4RG

AVAILABILITY OF COMPANION DOCUMENTS

Discussion points and questions for the first prescription of emergency contraception developed by the Faculty of Sexual and Reproductive Healthcare are available at the end of the original guideline document.

Electronic copies: Available in Portable Document Format (PDF) from the Faculty of Sexual and Reproductive Healthcare Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on July 5, 2005. This summary was updated by ECRI Institute on May 15, 2008.

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